From: Wasem, Russell
To: Baris, Reuben

Subject: RE: QUESTION ABOUT RODENTICIDE

Date: Friday, September 13, 2013 11:19:00 AM

Attachments: image001.png

Yeah def.

From: Baris, Reuben

Sent: Friday, September 13, 2013 11:04 AM

To: Wasem, Russell

Subject: RE: QUESTION ABOUT RODENTICIDE

Thanks. Hey also we (you me and Rosanna) should do a follow up lunch or regular leadership lunch to keep us all honest about what we learned/took away from OPM training. Interested?

From: Wasem, Russell

Sent: Friday, September 13, 2013 10:10 AM

To: Baris, Reuben

Subject: RE: QUESTION ABOUT RODENTICIDE

Nice one. I will plagiarize that response in the future. I have attached a q&a about rodenticide cancellation that you might find helpful for future stuff like this.

From: Baris, Reuben

Sent: Friday, September 13, 2013 9:30 AM

To: Alessio Benni

Cc: Laws, Meredith; Jennings, Susan; Wasem, Russell **Subject:** RE: QUESTION ABOUT RODENTICIDE

Dr. Benni,

I am providing answers to your questions below. Please let us know if you have any additional questions.

1. It is possible to use rodenticide products containing the active ingredient brodifacoum in the US, however the US EPA has taken significant measures to reduce the risk of using rodenticides such as brodifacoum. These safety measures (announced October 2012) will protect children from accidental exposure to rodent-control products. These measures will also reduce the risk of accidental poisonings of pets and wildlife. With the Agency's risk mitigation measures in place, rodenticide products will be safe, effective, and affordable for all consumers. Additional information on active ingredients impacted by these risk mitigation decisions can be found at the following website:

http://www.epa.gov/oppsrrd1/reregistration/rodenticides/finalriskdecision.htm.

To summarize, restrictions currently in place for products containing the active ingredient brodifacoum include: all products must contain at least at least 8 but not more than 16 pounds of bait, bait stations are required for all outdoor, above-ground placements of second-generation anticoagulant products, bait stations are required indoors if exposure to children, pets, or non-target animals is possible, distribution to and sales in "consumer" stores including grocery stores, drug stores, hardware stores, club stores will be prohibited. Additional label requirements are included on the website provided above.

2. The same restrictions are in place for bromadiolone as brodifacoum, both are second-generation anti-coagulant products. Therefore the same Sale and Package Distribution Restrictions, Minimum Package Size Requirements, and Use Restrictions are true for bromadiolone and brodifacoum and all other second-generation anti-coagulant products.

I hope this information answers your questions. Please contact me if you have any additional questions.

Kind regards, reuben

REUBEN BARIS | ACTING PRODUCT MANAGER 07 | U.S. EPA OFFICE OF PESTICIDE PROGRAMS, REGISTRATION DIVISION | PHONE: (703) 305-7356

From: Alessio Benni [mailto:alessio.benni@colkim.it]
Sent: Thursday, September 12, 2013 10:40 AM

To: Jennings, Susan

Cc: <u>AskCVM@fda.hhs.gov</u>; <u>jamula.john@epa.gov</u>; Wasem, Russell; Hobgood, Sherada; Thornton,

Eleanor; Baris, Reuben

Subject: R: QUESTION ABOUT RODENTICIDE

Dear Mrs Jennings , thank you so much for your prompt answer and for your great cooperation. Sincerely, Alessio Benni

Da: Jennings, Susan [mailto:Jennings.Susan@epa.gov]

Inviato: giovedì 12 settembre 2013 16:38

A: Alessio Benni; Hobgood, Sherada; Thornton, Eleanor; Baris, Reuben **Cc:** AskCVM@fda.hhs.gov; jamula.john@epa.gov; Wasem, Russell

Oggetto: RE: QUESTION ABOUT RODENTICIDE

Dr. Benni:

I am forwarding your email to Meredith Laws, who is the Chief of our Insecticide-Rodenticide Branch. Her branch will be able to provide you with a complete and accurate answer to your question.

Sincerely,

Susan Jennings
Public Health Coordinator, Office of Pesticide Programs
US Environmental Protection Agency
(706) 355-8574 (v)
(706) 355-8744 (f)

From: Alessio Benni [mailto:alessio.benni@colkim.it]
Sent: Thursday, September 12, 2013 10:20 AM

To: Hobgood, Sherada; Jennings, Susan; Thornton, Eleanor; Baris, Reuben

Cc: <u>AskCVM@fda.hhs.gov</u>; <u>jamula.john@epa.gov</u>; Wasem, Russell

Subject: QUESTION ABOUT RODENTICIDE

Importance: High

Dear Sir/Madam

my name is Alessio Benni, Regulatory Dept. of Colkim srl, an Italian Company manufacturing and distributing biocides and relate equipments.

I contact you because of I have a question concerning the drugs in USA.

An Italian company that manufactures drugs has informed me is not possible to use rodenticides for USA market (paraffin blocks or other physical forms) containing the active ingredient brodifacoum (CAS number 56073-10-0) for the deratization of the manufacturing plant where produces drugs.

This is because of the active ingredient brodifacoum (CAS number 56073-10-0) is not listed in the glossary attached and updated in your website at this link http://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/ucm113891.htm In Europe the active ingredient brodifacoum is used and authorized as active ingredient of rodenticides under Biocides Regulations (ex 98/8/EC Directive and 528/UE Regulation), but not authorized like Plant Protection Product under 1107/09 Regulation. So, my questions are:

- 1. Do you confirm is not possible to use rodenticides containing the active ingredient brodifacoum for the pest control (deratization) if the drugs will be market in USA?
- 2. It is possible, instead to use, for the scope above written, bromadiolone rodenticides baits (CAS number 28772-56-7)? It is instead listed in the glossary attached.
- 3. Considering the glossary of pesticide manual (June 2005) charged in your website, can I assume it how last version updated?

Thank you so much for your cooperation and help.

Best regards,

Dr. Alessio Benni

Responsabile controllo ed Assicurazione Qualità/Regulatory Affairs Quality control & Assurance Manager /Regulatory Affairs +39 051.799.445 int./ext. 24



Fax:+39 051.797.555 alessio.benni@colkim.it www.colkim.it

